

REMARKS

Claims 10-23 are currently being amended. Claims 1-28 are now pending in this application. In view of the amendments and following remarks, Applicants respectfully request reconsideration of the present application and submit that the application is in condition for allowance.

The Examiner rejected claims 10-23 under 35 U.S.C. § 101, as being directed to non-statutory subject matter. In the Office Action, claims 1-9, 20, and 25-28 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,272,480 (Tresp). In the Office Action, claims 10-15 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,956,501 (Brown). In the Office Action, claims 16-19 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,246,975 (Rivonelli). In the Office Action, claims 21 and 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tresp and further in view of Rivonelli. In the Office Action, claim 23 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Tresp and further in view of AIDA Case Selector (AIDA 1) and AIDA Explanations (AIDA 2). Applicants respectfully traverse these rejections.

I. Rejection of Claims Under 35 U.S.C. § 101

The Examiner rejected claims 10-23 under 35 U.S.C. § 101, as being directed to non-statutory subject matter. The Examiner stated that “claims 10-23 are not technologically embodied since the claims have not recited any limitations relating to a practical application in the technological arts and have merely claimed non-statutory subject matter (software).” (Office Action dated 8/10/2005, page 2). Applicants have amended claims 10-23 to indicate statutory subject matter. As a result, Applicants respectfully request that the Examiner withdraw the rejection of claims 10-23 under 35 U.S.C. § 101.

II. Rejection of Claims 1-9, 20, and 25-28 Under 35 U.S.C. § 102(e)

In the Office Action, claims 1-9, 20, and 25-28 were rejected under 35 U.S.C. § 102(e) as being anticipated by Tresp. Applicants respectfully traverse this rejection.

Claim 1 recites:

combining the plurality of biological processes to form a simulation of glucose metabolism in the context of multiple macronutrient metabolism

Claim 7 recites:

the instructions defining a simulation of glucose metabolism in the context of multiple macronutrient metabolism

Claim 25 recites:

combining the plurality of biological processes to form a simulation of at least one biological attribute of diabetes in the context of fat metabolism

Claim 26 recites:

combining the plurality of biological processes to form a simulation of at least one biological attribute of diabetes in the context of protein metabolism

Claim 27 recites:

the instructions defining a simulation of at least one biological attribute of diabetes in the context of fat metabolism

Claim 28 recites:

the instructions defining a simulation of at least one biological attribute of diabetes in the context of protein metabolism

On pages 4-5, of the Office Action dated 8/10/2005, the Examiner states:

As per claim 1, Tresp discloses ... combining the plurality of biological processes to form a simulation of glucose metabolism in the context of multiple macronutrient metabolism (col.: 2 lines: 10-22, col.: 4 lines: 33-41 multiple macronutrient metabolism correlates to “carbohydrates” within the reference).

Relative to claims 7-9, the Examiner states “the claims differ only in statutory basis to claims 1-3). (Office Action dated 8/10/2005, page 9). The Examiner further states:

As per claim 25, Tresp discloses ... combining the plurality of biological processes to form a simulation of at least one biological attribute of diabetes in the context of fat metabolism (col. 3 equation 3, col.: 2 lines: 10-23, col.: 4 lines: 33-41 Tresp’s disclosure is broader than the limitations set forth by this claim. Hence, it covers biological attributes of diabetes in the context of fat metabolism.)

(Office Action dated 8/10/2005, pages 10-11). The Examiner points to a similar basis for rejecting claims 26-28. Applicants respectfully disagree because Tresp fails to teach at least the limitations “a simulation of glucose metabolism” and “a simulation of at least one biological attribute of diabetes.”.

Tresp describes “a computerized neural network in order to obtain a valid model of systems that behave non-linearly and stochastically.” (Tresp, Col. 1, lines 46-48). As a result, Tresp describes in Equation 3 a neural network model of the dynamic system that includes a system error where the system error is determined using a linear system error model. (See Tresp, Col. 3, lines 21-51; FIG. 3). In paragraph [0030] of Applicants’ present disclosure, Applicants state that the “term ‘simulation’ is used herein to mean the numerical or analytical integration of a mathematical model. For example, simulation can mean the numerical integration of the mathematical model of the biological state defined by the above equation, i.e. $dx/dt=f(x, p, t)$.”

As Tresp recognizes:

measurements of influencing variables for the determination of the state of a technical or physiological system are very involved and complicated to implement, If one attempts to produce models

of such systems, an added complication is that these behave highly non-linearly and stochastically, so that computerized neural networks seem suitable for their modelling [sic]. ..., there is still the problem of predicting and training lacking measured values whose analytical solution leads to such complicated integrals that they are unmanageable.

(Tresp, Col. 1, lines 15-37; emphasis added). A neural network does not numerically or analytically integrate a mathematical model, and is therefore not a simulation. Instead, Tresp describes, “the computerized neural network being trained with the difference between the system error and a measured value that was measured at the respective point in time of the time series. In this way, it is assured that the neural network learns all non-linearities of the system.” Therefore, Tresp fails to teach at least the limitations “a simulation of glucose metabolism” and “a simulation of at least one biological attribute of diabetes.”

As a result, Tresp fails to disclose, suggest, or teach all of the limitations of claims 1, 7, and 25-28. An anticipation rejection cannot properly be maintained where the references used in the rejection do not disclose all of the recited claim elements. Applicants respectfully traverse any arguments posed by Examiner relative to claims 2-6 and 7-9 as they are allowable for at least the reasons outlined above relative to claims 1 and 7. Therefore, Applicants respectfully request withdrawal of the rejection of claims 1-9 and 25-28.

Claim 20 recites:

a first biological process from the plurality of biological processes being associated with metabolism of at least two from the group of carbohydrates, fats and proteins, a second biological process from the plurality of biological processes being associated with metabolism of glucose.

On pages 9-10, of the Office Action dated 8/10/2005, the Examiner states:

As per claim 20, Tresp discloses ... a first biological process from the plurality of biological processes being associated with metabolism of at least two from the group of carbohydrates, fats and proteins, a second biological process from the plurality of

biological processes being associated with metabolism of glucose
(col.: 2 lines: 10-23, col.: 4 lines: 33-41).

Applicants respectfully disagree because Tresp fails to teach at least the limitation “a first biological process from the plurality of biological processes being associated with metabolism of at least two from the group of carbohydrates, fats and proteins.”

Tresp describes “time series of administered insulin doses, of the quantity of food, physical training and the current as well as the preceding estimated blood sugar value are made available for training the model.” (Tresp, Col. 2, lines 22-25). Tresp further describes:

Determinant influencing variables for this blood sugar-insulin metabolism are, in detail, the times and dosage amounts of insulin injections, the times and amounts of food ingestion (basal insulin u_t^1 and normal insulin u_t^2), the times and amounts of food ingestion (fast u_t^3 , medium u_t^4 and slow u_t^5 carbohydrates), the points in time and duration of physical exercise (regular u_t^6 or intensive u_t^7) and the blood sugar level y_t (measured multiply per day).

(Tresp, Col. 2, lines 22-25). As a result, Tresp describes influencing variables of metabolism of groups of carbohydrates. Therefore, Tresp fails to teach at least the limitation “a first biological process from the plurality of biological processes being associated with metabolism of at least two from the group of carbohydrates, fats and proteins.”

As a result, Tresp fails to disclose, suggest, or teach all of the limitations of claim 20. An anticipation rejection cannot properly be maintained where the references used in the rejection do not disclose all of the recited claim elements. Therefore, Applicants respectfully request withdrawal of the rejection of claim 20.

III. Rejection of Claims 10-15 Under 35 U.S.C. § 102(b)

In the Office Action, claims 10-15 were rejected under 35 U.S.C. § 102(b) as being anticipated by Brown. Applicants respectfully traverse this rejection.

Claim 10 recites:

providing a plurality of predefined defect indicators, each predefined defect indicator from the plurality of predefined defect indicators being uniquely associated with a defect from a plurality of defects associated with a disease state of diabetes, each defect from the plurality of defects being associated with at least one biological process from the set of biological processes.

On pages 15-16, of the Office Action dated 8/10/2005, the Examiner states:

As per claim 10, Brown discloses ... a plurality of predefined defect indicators, each predefined defect indicator from the plurality of predefined defect indicators being uniquely associated with a defect from a plurality of defects associated with a disease state of diabetes, each defect from the plurality of defects being associated with at least one biological process from the set of biological processes (col.: 4 top table. Predefined defect indicators are shown in column 2 of the table).

Applicants respectfully disagree because Brown fails to teach at least the limitation “each predefined defect indicator from the plurality of predefined defect indicators being uniquely associated with a defect from a plurality of defects associated with a disease state of diabetes”.

Brown describes a “system and method for simulating a disease control parameter and for predicting the effect of patient self-care actions on the disease control parameter.” (Brown, Col. 1, lines 8-10). Brown further describes patient self-care parameters that, according to column 2 of the table at the top of Col. 4, include insulin, diet, exercise, allergens, inhaled bronchial dilators, anti-inflammatory medications, metabolism altering medications, stress reduction, blood pressure medications, lipid lowering medications, anti-depressant medications, cigarettes smoked, and coping behaviors. In paragraph [0128] of Applicants’ present disclosure Applicants

state that the “term ‘defect’ as used herein means an imperfection, failure, or absence of a biological variable or a biological process associated with a disease state.” None of these self-care parameters is a defect indicator or a defect. Therefore, Brown fails to teach at least the limitation “each predefined defect indicator from the plurality of predefined defect indicators being uniquely associated with a defect from a plurality of defects associated with a disease state of diabetes.”

As a result, Brown fails to disclose, suggest, or teach all of the limitations of claim 10. An anticipation rejection cannot properly be maintained where the references used in the rejection do not disclose all of the recited claim elements. Applicants respectfully traverse any arguments posed by Examiner relative to claims 11-15 as they are allowable for at least the reasons outlined above relative to claim 10. Therefore, Applicants respectfully request withdrawal of the rejection of claims 10-15.

IV. Rejection of Claims 16-19 and 24 Under 35 U.S.C. § 102(e)

In the Office Action, claims 16-19 were rejected under 35 U.S.C. § 102(e) as being anticipated by Rivonelli. Applicants respectfully traverse this rejection.

Claim 16 recites:

providing a plurality of predefined defect indicators, each predefined defect indicator from the plurality of predefined defect indicators being uniquely associated with a defect from a plurality of defects associated with a disease state, each defect from the plurality of defects being associated with at least one biological process from a set of biological processes.

On page 20, of the Office Action dated 8/10/2005, the Examiner states:

As per claim 16, Rivonelli discloses ... a plurality of predefined defect indicators, each predefined defect indicator from the plurality of predefined defect indicators being uniquely associated with a defect from a plurality of defects associated with a disease state, each defect from the plurality of defects being associated

with at least one biological process from a set of biological processes (col.: 16 lines 17-18, col.: 23 lines: 30-36 When the generation method is performed, it provides a description of all of the findings).

Applicants respectfully disagree because Rivonelli fails to teach at least the limitation “each predefined defect indicator from the plurality of predefined defect indicators being uniquely associated with a defect from a plurality of defects associated with a disease state of diabetes.”

Rivonelli describes that “[t]he software of the present invention presents a patient by using text, illustrations, still pictures, and video. The examinee questions and examines the simulated patient, reaches conclusions about the situation, and suggests treatment options.” (Rivonelli, Col. 12, lines 48-52). Rivonelli further describes that “[t]he model emphasizes diagnostic and management issues, variability in populations, and time. It describes consequences of anatomic and physiologic processes, but largely omits anatomic and physiologic reasoning as such.” (Rivonelli, Col. 15, lines 10-13; emphasis added). Rivonelli still further describes that “[t]he following major entities appear in the design: Populations, Records, Health States, Findings, Courses of Action, and Agents of Change.” As a result, Rivonelli describes that:

Health States include all normal health states; classic disease presentations; early, subtle, or late disease presentations; and some disease combinations. Health States also include groups of Health States with shared characteristics, such as cardiovascular diseases and diseases of glucose intolerance.

(Rivonelli, Col. 15, lines 61-66). Rivonelli also describes that “Agents include physical, chemical, biological, behavioral, and social events capable of influencing Health States or Findings. These Agents can be therapeutic, injurious, or both. Agent descriptions include data about intake, metabolism, and excretion, as applicable. For instance, a long-acting steroid is a chemical agent.” (Rivonelli, Col. 18, lines 21-26). Rivonelli additionally describes that “Agents(e.g., drugs) make a difference only when used in the context of a Course of Action.” (Rivonelli, Col. 21, lines 38-39).

In paragraph [0128] of Applicants' present disclosure Applicants state that the "term 'defect' as used herein means an imperfection, failure, or absence of a biological variable or a biological process associated with a disease state." The "Health States" and "Agents" described by Rivonelli are not a defect indicator or a defect. Thus, Rivonelli does not teach "each predefined defect indicator from the plurality of predefined defect indicators being uniquely associated with a defect from a plurality of defects associated with a disease state." Therefore, Rivonelli fails to teach at least the limitation "providing a plurality of predefined defect indicators, each predefined defect indicator from the plurality of predefined defect indicators being uniquely associated with a defect from a plurality of defects associated with a disease state, each defect from the plurality of defects being associated with at least one biological process from a set of biological processes."

As a result, Rivonelli fails to disclose, suggest, or teach all of the limitations of claim 16. An anticipation rejection cannot properly be maintained where the references used in the rejection do not disclose all of the recited claim elements. Applicants respectfully traverse any arguments posed by Examiner relative to claims 17-19 as they are allowable for at least the reasons outlined above relative to claim 16. Therefore, Applicants respectfully request withdrawal of the rejection of claims 16-19.

V. Rejection of Claims 21-22 Under 35 U.S.C. § 103(a)

In the Office Action, claims 21 and 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tresp and further in view of Rivonelli. Applicants respectfully traverse this rejection because the Examiner has failed to present a prima facie case of obviousness. MPEP § 2143 states:

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

At a minimum, the Examiner has failed to demonstrate that Tresp and Rivonelli in combination disclose, teach, or suggest all of the claim limitations as recited in Claims 21-22.

As discussed in Section II. above, Tresp fails to teach the limitation “a first biological process from the plurality of biological processes being associated with metabolism of at least two from the group of carbohydrates, fats and proteins” of claim 20. Rivonelli describes a “computer implemented simulation and evaluation method [that] simulates interventions to a patient by a user, and evaluates the interventions responsive to predetermined criteria and the interventions.” (Rivonelli, Abstract). Rivonelli describes that “[a]gent descriptions include data about intake, metabolism, and excretion, as applicable.” (Rivonelli, Col. 18, lines 24-25). Rivonelli makes no other mention of metabolism and fails to mention carbohydrates, fats and proteins at all. As a result, neither Tresp nor Rivonelli disclose, suggest, or teach all of the limitations of claim 20. An obviousness rejection cannot be properly maintained where the references used in the rejection do not disclose all of the recited claim elements. Therefore, Applicants respectfully request withdrawal of the rejection of claims 21 and 22 which depend from claim 20.

VI. Rejection of Claim 23 Under 35 U.S.C. § 103(a)

In the Office Action, claim 23 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Tresp and further in view of AIDA 1 and AIDA 2. Applicants respectfully traverse this rejection because the Examiner has failed to present a prima facie case of obviousness according to MPEP § 2143. At a minimum, the Examiner has failed to demonstrate that Tresp, AIDA 1, and AIDA 2 in combination disclose, teach, or suggest all of the claim limitations as recited in Claim 23.

As discussed in Section II. above, Tresp fails to teach the limitation “a first biological process from the plurality of biological processes being associated with metabolism of at least two from the group of carbohydrates, fats and proteins” of claim 20. AIDA 1 shows a carbohydrate input text box. (AIDA 1, page 3). AIDA 2 states “[d]epending on the carbohydrate

content of the various meals and the amount of insulin injected, ..., the model is able to simulate a blood glucose profile." (AIDA 2, page 3). Neither AIDA 1 nor AIDA 2 mentions fats or proteins at all. As a result, neither Tresp, AIDA 1, nor AIDA 2 disclose, suggest, or teach all of the limitations of claim 20. An obviousness rejection cannot be properly maintained where the references used in the rejection do not disclose all of the recited claim elements. Therefore, Applicants respectfully request withdrawal of the rejection of claim 23 which depends from claim 20.

For the foregoing reasons, it is submitted that all of the claims that have been examined in this application should be in condition for allowance.

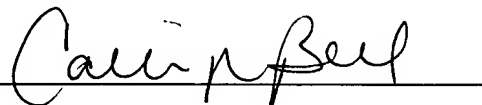
The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

Date November 9, 2005

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By

A handwritten signature in cursive script, appearing to read "Callie M. Bell", written over a horizontal line.

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